REMARKS

Claims 1-43 are pending. Claims 9-15 and 20-42 are under examination.

Rejection Under 35 U.S.C. § 101 and § 112, First Pargraph

The rejection of claims 9-15 and 20-42 under 35 U.S.C. § 101 and under § 112, first paragraph, as allegedly lacking utility are respectfully traversed. Applicant respectfully maintains, for the reasons of record, that the claimed nucleic acids have a specific, substantial and credible utility.

In re Fischer, Case No. 04-1465 (Fed. Cir. Sept. 9, 2005), the U.S. Court of Appeals for the Federal Circuit, noting that the Supreme Court's precedential decision in *Brenner v. Mason* does not define the terms "specific" and "substantial," took the opportunity to clarify the two-pronged test for utility under 35 U.S.C. §101. The Court indicated that, to satisfy the "substantial" utility requirement, an asserted use must show that the claimed invention has a significant and presently available public benefit. Turning to the "specific" utility requirement, the Court explained an application must disclose a use which is not so vague as to be meaningless. Thus, in addition to providing a "substantial" utility, an asserted use must also show the claimed invention can provide a well-defined and particular benefit to the public. Applying these principles, the Court found the asserted utilities for ESTs met neither the substantial nor the specific test but were merely a starting point for further research, providing no presently available benefit. With regard to the "specific" utility requirement, the Court found Fisher **had failed to assert any utilities distinguishing the claimed ESTs from the more than 32,000 ESTs disclosed in the application or any EST derived from any organism**. The Court held that, **absent identification of a function for the underlying protein-encoding genes, the claimed ESTs had not been researched and understood to the point of providing an immediate, well-defined, real-world benefit to the public meriting the grant of a patent**.

Applicant respectfully maintains that the specification teaches a substantial and specific utility and is clearly distinguishable from the EST's at issue in *In re Fischer*. The *In re Fisher* decision makes it clear that the threshold for utility of a DNA sequence is the **identification of a function for the underlying protein-encoding genes.** Analysis of the Nope sequence revealed

that the protein encoded by the Nope nucleic acid sequence contains four immunoglobulin domains and five fibronectin-type domains, has structural similarity to DCC, Punc and NCAM, and most closely resembles cell adhesion molecules (page 46, lines 8-17). The specification further teaches the function of these structurally related proteins as axonal guidance receptors (page 49, line 22, to page 50, line 7). The specification also teaches the developmental expression of Nope, including its expression in cells of the nervous system (Example II, pages 46-48, in particular page 47, line 27, to page 48, line 16). The specification clearly provides an explicit teaching of a specific, substantial and credible utility of the Nope polynucleotide in that it encodes a protein expressed in the nervous system and that functions as an axonal guidance receptor.

The specification teaches that Nope is expressed in the developing mouse embryo in the notochord, in developing muscle tissues and in the developing nervous system (page 47, line 10, to page 48, line 16). Nope expression is concentrated in the ventricular zone in the brain and in the hippocampus, the piriform cortex, thalamic nucleic and foliae of the cerebellum of adult brain (page 48, lines 3-16). The specification teaches that Nope functions in cells of the nervous system that arise late in gestation (page 48, lines 8-11). Applicant maintains that the specification provides a clear and credible teaching of a functional role of Nope in neuronal development.

With regard to the claimed Nope encoding nucleic acids, the specification teaches that the nucleic acid encodes a polypeptide having four immunoglobulin domains and five fibronectin-type domains, both of which are well characterized structural domains (page 46, lines 8-17). In addition, the specification teaches that Nope is related to axonal guidance receptors (page 49, line 22, to page 50, line 3). Furthermore, the specification teaches that Nope is expressed in the nervous system, consistent with its role in axonal guidance. Therefore, the claimed nucleic acids encoding Nope are correlated in the specification with well known structural motifs, proteins with known function, and tissue expression consistent with that function.

As discussed above, Applicant respectfully submits that the immunoglobulin and fibronectin domains are well known structural motifs. While it is known that proteins with different sequences can fold similarly and have similar functions and can have similar functions

with different structures, as asserted in the Office Action, Applicant is unaware of the basis for the assertion in the Office Action on page 4 that proteins with very similar sequence fold up differently and respectfully request that the Examiner provide evidence that proteins with very similar sequences fold differently. Even so, the immunoglobulin and fibronectin domains are well characterized structural domains present on cell surface receptors and diffusible ligands that function as binding domains (page 12, line 7, to page 14, line 29). A subgroup of the immunoglobulin superfamily has been associated with migration and guidance of axonal growth cones (page 13, line 1, to page 14, line 29).

Applicant respectfully maintains that, at least for the reasons described above, the claimed nucleic acids have a specific and substantial utility. Applicant respectfully submits that, based on the teachings in the specification and what was well known to those skilled in the art, one of ordinary skill in the art would have understood that the claimed Nope encoding nucleic acid molecules have a specific, substantial and credible utility. Accordingly, Applicant respectfully requests that the utility rejection under 35 U.S.C. § 101 and 112 be withdrawn.

Rejection Under 35 U.S.C. § 112, First Paragraph

The rejection of claims 9, 10 and 14 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description is respectfully traversed. Applicant maintains, for the reasons of record, that the specification provides sufficient description and guidance for the claimed nucleic acids.

As discussed previously, the specification teaches that a modification of a nucleic acid can include one or several nucleotide additions, deletions or substitutions with respect to a reference sequence, including a substantially the same nucleotide sequence that can hybridize under moderately stringent or higher stringency conditions (page 9, lines 16-30). The specification also teaches various stringency conditions (page 24, line 15, to page 25, line 18). Therefore, Applicant respectfully maintains that the specification provides sufficient description and guidance for the claimed nucleic acid molecules and modifications thereof. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

In light of the remarks herein, Applicant submits that the claims are now in condition for allowance and respectfully requests a notice to this effect. The Examiner is invited to call the undersigned agent if there are any questions.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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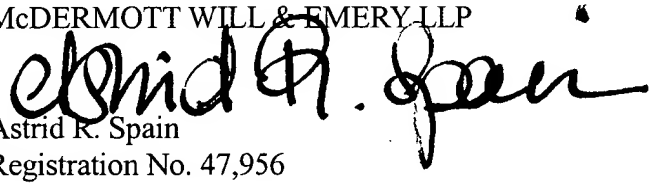

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SDO 42731-1.066655.0024